6 510(k) Summary for Vendys Model 5000 B/BC

Sponsor

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Date Prepared: June 28th, 2007

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Device Classification:

Proprietary name:	Vendys Model 5000 B/BC
Common/Usual name:	Digital Thermal Monitor
Classification Name:	Programmable Diagnostic Computer
Classification:	
Product Code:	DQK
Regulation Number:	CFR 870.1425
Class:	II
Panel:	Cardiovascular

Predicate Devices

Manufacturer	Device	Approval No.
Vivant Medical	VivaTherm Temp Monitor Sys	K031556
Endocare, Inc.	Endocare Electronic Therm Sys	K961365
URI Therm-X, Inc	URI TX-100 Multi Chan Thermo	K843381
Itamar Medical	Endo PAT 2000	K032519

6 510(k) Summary for Vendys Model 5000 B/BC (cont'd)

Device Description

The VENDYS Model 5000 B/BC is a non-invasive, Programmable Diagnostic Computer device capable of providing digital thermal monitoring of multiple digits that can aid in studies of vascular function and evaluation of future cardiovascular risk.

The device provides continuous and simultaneous monitoring of skin surface temperature at multiple digits (e.g. fingertips on the study and control hands). It displays temperature changes before, during and after a reactive hyperemia procedure, and calculates multiple indices based on temperature changes.

The surface temperature signal (1 or 2 channels) is recorded at the digit (e.g. fingertip) and processed in the Vendys Model 5000 B electronics module. The signal processing electronics module (Vendys Model 5000 B) is attached to a PC computer via a standard USB cable through a USB port. The Vendys Data Acquisition and Analysis software is necessary to calculate, display, and archive the test data and is intended to be loaded on an IBM-compatible computer (notebook or desktop). The Vendys software records the signals from the Vendys Model 5000 B electronics module, displays a plot of the temperature response before, during and after a reactive hyperemia procedure, and calculates multiple indices based on temperature changes. These temperature indices and the temperature plot are further explained in Section 12 of the submission. The Vendys software program also allows user input of other pertinent patient information and provides the operator with instructions for use.

Intended Use

The VENDYS Model 5000 B/BC is a non-invasive, digital temperature monitoring device. The device provides continuous monitoring of body surface temperature at multiple sites simultaneously (e.g. fingertips on the study and control hands).

It is intended to use for measurement of vascular reactivity by monitoring temperature changes before, during and after a reactive hyperemia test using a 2-5 minute cuff occlusion procedure.

6 510(k) Summary for Vendys Model 5000 B/BC (cont'd)

Performance Standards

The following FDA Recognized Consensus Standards have been adopted in the course of development.

Item 80: ASTM E112-00, Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature. (General Plastic/General Hospital)

Date of Standard: 2000

Recognition List Number: 007
Effective Date: 05/31/2002
Part B: Supplementary Information

CDRH Office and Division Associated with Recognized Standards:
Office of Device Evaluation (ODE)
Div of Anesthesiology, Gen. Hospital, Infection Control & Dental Device

In addition the Vendys Model 5000 B/C has adopted the following voluntary standards in the course of development

-IEC 60601-1:1998+A1:1991+:1995
-IEC 60601-1-2:1993
-ISO10993

Technological Characteristics and Substantial Equivalence

Endothelix, Inc. believes that, based on verification, validations, and safety and performance testing results, the Vendys Model 5000 B/BC is substantially equivalent to other legally marketed devices and to the standard procedures cited above without raising new safety and/or effectiveness issues. Moreover, any differences in their technological characteristics that do exist would not have a significant effect on the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2007

Mr. Douglas W. Blakely
Vice President-Director Clinical & Regulatory Affairs
Endothelix, Incorporated
8275 El Rio, Suite 100
Houston, Texas 77054

Re: K060980
Trade/Device Name: Vendys Model 5000 B/BC
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II
Product Code: DQK
Dated: June 4, 2007
Received: July 2, 2007

Dear Mr. Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

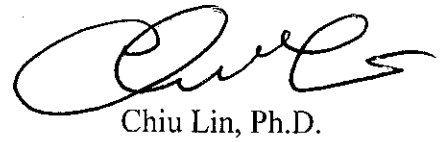
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060980

1 of 1

5 Indications For Use Statement

510(k) Number: K060980

Device Name: Vendys Model 5000 B/BC

The VENDYS Model 5000 B/BC is a non-invasive, digital temperature monitoring device. The device provides continuous monitoring of body surface temperature at multiple sites simultaneously (e.g. fingertips on the study and control hands).

It is intended to use for measurement of vascular reactivity by monitoring temperature changes before, during and after a reactive hyperemia test using a 2-5 minute cuff occlusion procedure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K060980